K072226

510(k) SUMMARY

DEC 1 0 2007

GENERAL INFORMATION

Trade Name	IMPIX Interbody Device
Common Name	intervertebral body fusion device
Classification Name	intervertebral body fusion device - cervical intervertebral body fusion device - lumbar
Class	II
Product Code	ODP MAX
21 CFR section	888.3080
Device panel	Orthopedic
Legally marketed predicate devices	1. BAK/C Vista Interbody Fusion - peek-optima lt1, Zimmer Spine, Inc (P980048 S003) 2. BRANTIGEN I/F CAGE, DePuy Spine Inc, (P960025) 3. LT-CAGE PEEK LUMBAR - peek-optima lt1, Medtronic (P970015 S022) 4. BAK INTERBODY LUMBAR FUSION - 65% peek optima/35% carbon fiber, Zimmer Spine (P950002 S011)
Submitter	MEDICREA™ Technologies Z.I. Chef de Baie 17000 La Rochelle, France
Contact	J.D. Webb 1001 Oakwood Blvd Round Rock, TX 78681 512-388-0199

DEVICE DESCRIPTION

The IMPIX Cervical Interbody devices consist of implants with a convexity on the upper surface with anti-migration upper ridging and lower pins. The IMPIX Cervical Interbody device has a D-form with two openings that allow the surgeon to fill it with bone graft. In order to adapt to the varying morphology of patients, both IMPIX Cervical Interbody devices are available in various sizes. The IMPIX Cervical Interbody device is machined from PEEK OPTIMA LT1.

The IMPIX Lumbar Interbody device is bi-convex in the sagittal plane. It possesses teeth on both superior and inferior surfaces that assist in the anchorage and stability of the device to the bone of the vertebrae. The upper and lower aspects of the IMPIX-L are open, to allow the surgeon to pack the device with bone graft prior to insertion. Lateral holes exist to allow bone growth through the device. In order to adapt to the varying morphology of patients, the IMPIX Lumbar Interbody devices are available in various sizes. The IMPIX Lumbar Interbody device is machined from PEEK OPTIMA LT1.

INTENDED USE

IMPIX-C Cervical Interbody Device is indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one disc level from C3-C7. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. This device is to be used with autogenous bone graft.

IMPIX-C Cervical Interbody Device is to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

IMPIX-L Lumbar Interbody Device is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). This device is to be used with autogenous bone graft.

IMPIX-L Lumbar Interbody Device is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

PERFORMANCE DATA

Tests performed according to ASTM F2077 indicate that the IMPIX Interbody Fusion devices meet required mechanical strengths.

SUBSTANTIAL EQUIVALENCE

The IMPIX Interbody Fusion devices are similar in design, material, and intended use to its predicate devices that have been cleared by FDA for intervertebral body fusion.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 0 2007

Medicrea Technologies
% The Orthomedix Group, Inc.
J.D. Webb
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K072226
Trade/Device Name: IMPIX Interbody Devices
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: MAX, ODP
Dated: November 28, 2007
Received: December 3, 2007

Dear J.D. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K072226

Device Name: IMPIX Interbody Devices

Indications for Use:

IMPIX-C Cervical Interbody Device is indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one disc level from C3-C7. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. This device is to be used with autogenous bone graft.

IMPIX-C Cervical Interbody Device is to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

IMPIX-L Lumbar Interbody Device is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). This device is to be used with autogenous bone graft.

IMPIX-L Lumbar Interbody Device is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Brenner

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072226